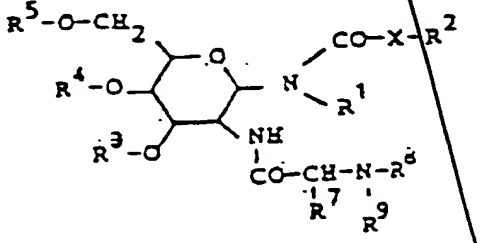
Claims

1. Pharmaceutical composition which comprises an immunogenic agent derived from *Helicobacter* and at least one compound selected from:

(i) saponins purified from an extract of *Quillaja saponaria*;

(ii) cationic lipids or a salt of the latter; the said lipids being weak inhibitors of protein kinase C and having a structure which includes a lipophilic group derived from cholesterol, a bonding group selected from carboxyamides and carbamoyls, a spacer arm consisting of a branched or unbranched linear alkyl chain of 1 to 20 carbon atoms, and a cationic amine group selected from primary, secondary, tertiary and quaternary amines, on condition that these lipids are not provided in the form of liposomes when the said composition contains no saponin or glycolipopeptide of formula (I); and

(iii) glycolipopeptides of formula (I):



(I)

in which

R^1 represents an alkyl residue saturated or unsaturated once or several times and comprising from 1 to 50 carbon atoms,

X represents $-CH_2-$, $-O-$ or $-NH-$,

R^2 represents a hydrogen atom or an alkyl residue saturated or unsaturated once or

several times and comprising from 1 to 50 carbon atoms,

R^3, R^4 and R^5 each represent, independently of each other, a hydrogen atom or an acyl-CO-R^6 residue in which R^6 represents an alkyl residue having from 1 to 10 carbon atoms,

R^7 represents a hydrogen atom, a C_1-C_7 alkyl, hydroxymethyl, 1-hydroxyethyl, mercaptomethyl, 2-(methylthio)ethyl, 3-aminopropyl, 3-ureidopropyl, 3-guanidylpropyl, 4-aminobutyl, carboxymethyl, carbamoylmethyl, 2-carboxyethyl, 2-carbamoylethyl, benzyl, 4-hydroxybenzyl, 3-indolylmethyl or 4-imidazolylmethyl group,

R^8 represents a hydrogen atom or a methyl group, and

R^9 represents a hydrogen atom, an acetyl, benzoyl, trichloroacetyl, trifluoroacetyl, methoxycarbonyl, t-butyloxycarbonyl or benzyloxycarbonyl group, and

R^7 and R^8 may, when they are taken together, represent a $-CH_2-CH_2-CH_2-$ group.

2. Composition according to Claim 1, which comprises at least two compounds, a first compound being selected from the saponins purified from an extract of *Quillaja saponaria* and a second compound being selected from cationic lipids or a salt of the latter; the said lipids being weak inhibitors of protein kinase C and having a structure which includes a lipophilic group derived from cholesterol, a bonding

group selected from carboxyamides and carbamoyls, a spacer arm consisting of a branched or unbranched linear alkyl chain of 1 to 20 carbon atoms, and a cationic amine group selected from primary, secondary, tertiary and quaternary amines.

3. Composition according to Claim 1 or 2, in which the compound is a saponin which is the QS-21 fraction purified from a *Quillaja saponaria* extract.

4. Composition according to Claim 1 or 2, in which the compound is a cationic lipid made in the form of a dispersion.

5. Composition according to Claim 1, 2 or 4, in which the compound is a cationic lipid which is 3-beta-[N-(N',N'-dimethylaminoethane)carbamoyl]cholesterol(DC-chol) or a salt of the latter.

6. Composition according to Claim 1, in which the compound is a glycolipopeptide which is N-(2-L-leucin-amido-2-deoxy-β-D-glucopyranosyl)N-octadecyl-dodecanoylamide (Bay R1005).

7. Composition according to one of Claims 1 to 6, in which the immunogenic agent derived from *Helicobacter* is selected from a preparation of inactivated *Helicobacter* bacteria, a *Helicobacter* cell lysate, a peptide and a polypeptide from *Helicobacter* in purified form.

8. Composition according to Claim 7, in which the immunogenic agent derived from *Helicobacter* is the UreB or UreA subunit of *Helicobacter* urease.

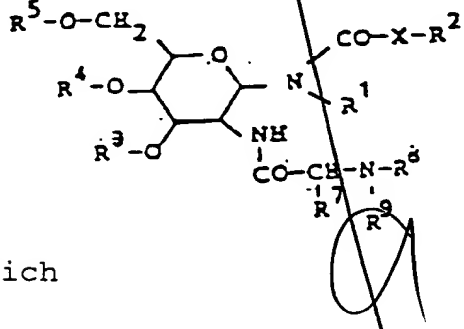
9. Composition according to one of Claims 1 to 8, in which the immunogenic agent is derived from *Helicobacter pylori*.

10. Use of an immunogenic agent derived from *Helicobacter* and of at least one compound selected from:

(i) saponins purified from an extract of *Quillaja saponaria*;

(ii) cationic lipids or a salt of the latter; the said lipids being weak inhibitors of protein kinase C and having a structure which includes a lipophilic group derived from cholesterol, a bonding group selected from carboxyamides and carbamoyls, a spacer arm consisting of a branched or unbranched linear alkyl chain of 1 to 20 carbon atoms, and a cationic amine group selected from primary, secondary, tertiary and quaternary amines, on condition that these lipids are not provided in the form of liposomes when the said composition contains no saponin or glycolipopeptide of formula (I); and

(iii) glycolipopeptides of formula (I):



(I)

in which

R^1 represents an alkyl residue saturated or unsaturated once or several times and comprising from 1 to 50 carbon atoms,

X represents $-CH_2-$, $-O-$ or $-NH-$,

R^2 represents a hydrogen atom or an alkyl residue saturated or unsaturated once or several times and comprising from 1 to 50 carbon atoms,

R^3, R^4 and R^5 each represent, independently of each other, a hydrogen atom or an acyl-$CO-R^6$ residue in which R^6 represents an alkyl

residue having from 1 to 10 carbon atoms,

R^7 represents a hydrogen atom, a C_1-C_7 alkyl, hydroxymethyl, 1-hydroxyethyl, mercaptomethyl, 2-(methylthio)ethyl, 3-aminopropyl, 3-ureidopropyl, 3-guanidylpropyl, 4-aminobutyl, carboxymethyl, carbamoylmethyl, 2-carboxyethyl, 2-carbamoylethyl, benzyl, 4-hydroxybenzyl, 3-indolylmethyl or 4-imidazolylmethyl group,

R^8 represents a hydrogen atom or a methyl group, and

R^9 represents a hydrogen atom, an acetyl, benzoyl, trichloroacetyl, trifluoroacetyl, methoxycarbonyl, t-butyloxycarbonyl or benzyloxycarbonyl group, and

R^7 and R^8 may, when they are taken together, represent a $-CH_2-CH_2-CH_2-$ group;

in the manufacture of a pharmaceutical composition capable of inducing a T helper 1 (Th1) type immune response against *Helicobacter*.

11. Use according to Claim 10, of an immunogenic agent derived from *Helicobacter* and of at least two compounds, a first compound being selected from the saponins purified from an extract of *Quillaja saponaria* and a second compound being selected from cationic lipids or a salt of the latter; the said lipids being weak inhibitors of protein kinase C and having a structure which includes a lipophilic group derived from cholesterol, a bonding group selected from carboxyamides and carbamoyls, a spacer arm consisting

of a branched or unbranched linear alkyl chain of 1 to 20 carbon atoms, and a cationic amine group selected from primary, secondary, tertiary and quaternary amines.

12. Use according to Claim 10 or 11, in which the compound is a saponin which is the QS-21 fraction purified from a *Quillaja saponaria* extract.

13. Use according to Claim 10 or 11, in which the compound is a cationic lipid made in the form of a dispersion.

14. Use according to Claim 10, 11 or 13, in which the compound is 3-beta-[N-(N',N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-chol) or a salt of the latter.

15. Use according to Claim 10, in which the compound is a glycolipopeptide which is N-(2-L-leucin-amido-2-deoxy -β-D-glucopyranosyl) N-octadecyl-dodecanoylamide (Bay R1005).

16. Use according to one of Claims 10 to 15, in which the Th1 type immune response is measured in mice and is characterized either (i) by a ratio of the ELISA IgG2a : IgG1 titres greater than or equal to 1 : 100 or (ii) by a ratio of the ELISA IgG2a : IgA titres greater than or equal to 1 : 100.

17. Use according to Claim 16, in which the Th1 type immune response is measured in mice and is characterized either (i) by a ratio of the ELISA IgG2a : IgG1 titres greater than or equal to 1 : 10 or (ii) by a ratio of the ELISA IgG2a : IgA titres greater than or equal to 1 : 10.

18. Use according to Claim 17, in which the Th1 type immune response is measured in mice and is characterized either (i) by a ratio of the ELISA IgG2a : IgG1 titres greater than or equal to 1 : 2 or (ii) by a ratio of the ELISA IgG2a : IgA titres greater than or equal to 1 : 2.

19. Use according to one of Claims 10 to 18, in which the immunogenic agent derived from *Helicobacter*

is selected from a preparation of inactivated *Helicobacter* bacteria, a *Helicobacter* cell lysate, a peptide and a polypeptide from *Helicobacter* in purified form.

20. Use according to Claim 19, in which the immunogenic agent derived from *Helicobacter* is the UreB or UreA subunit of *Helicobacter* urease.

21. Use according to one of Claims 10 to 20, in which the immunogenic agent is derived from *Helicobacter pylori*.

22. Use according to one of Claims 10 to 21, in which the pharmaceutical composition is intended to be administered by the systemic route.

23. Use according to Claim 22, in which the pharmaceutical composition is intended to be administered by the strict systemic route.

24. Use according to Claim 22 or 23, in which the pharmaceutical composition is intended to be administered by the systemic route in the part of a mammal, in particular of a primate, situated under its diaphragm.

25. Use according to one of Claims 22 to 24, in which the pharmaceutical composition is intended to be administered by a systemic route in the dorsolumbar region of a mammal, in particular a primate.

26. Use according to one of Claims 22 to 25, in which the pharmaceutical composition is intended to be administered by a systemic route selected from the subcutaneous route, the intramuscular route and the intradermal route.

27. Use according to one of Claims 10 to 26, in which the pharmaceutical composition is intended to be administered twice or three times by the systemic route during the same treatment, to prevent or treat a *Helicobacter* infection.

28. Conjoint use of an immunogenic agent derived from *Helicobacter* and of a compound capable of promoting the induction of a T helper 1 (Th1) type

immune response against *Helicobacter*, in the manufacture of a pharmaceutical composition intended to be administered by the systemic route to prevent or treat a *Helicobacter* infection.

add A1